REMARKS

Applicants request reconsideration of this application in view of the foregoing claim changes and these remarks.

I. Status of the claims

Claims 1-31 and 35-40 were pending, with claim 1-26, 30, and 39 withdrawn from consideration. With this submission, claims 1, 27 and 36 are amended and claims 41-55 are added. Upon entry of this response, therefore, claims 1-31 and 35-53 will be pending. In addition, applicants request rejoinder of method claims 1-12, which now recite the use of a therapeutic composition according to claim 27. Thus, applicants seek consideration of claims 1-12, 27-29, 31, 35-38, and 40-55 together.

II. Claim amendments

The specification amply supports the proposed claim revisions and additions, as the following claim/specification concordance illustrates:

Claim	Support
Claims 27, 36 ("wherein the composition complies with standards of purity and quality control required for administration to humans")	Para. [0045]
Claim 41	Para. [0049]
Claim 42	Para. [0045]
Claim 43	Paras. [0049, 53]
Claim 44	Paras. [0047, 56]
Claim 45	Para. [0048]
Claim 46	Paras. [0048, 52, 53]
Claim 47	Para. [0054]
Claim 48	Para. [0054]
Claim 49	Para. [0060]
Claim 50	Para. [0048]
Claim 51	Para. [0046]
Claim 52	Para. [0046]

Claim 53	Para. [0010]
Claim 54	Para. [0060]
Claim 55	Para. [0060]

III. Rejoinder of method claims 1-12

Since the subject application is the U.S. national stage of PCT/US2003/032827, the question of unity of invention (restriction between claim groups) is governed by PCT rules. The previous restriction whereby method claims 1-12 were withdrawn is inappropriate for the amended claims, pursuant to PCT Rules 13.1 and 13.2. That is, those claims and independent claim 27 relate to a single, general inventive concept by virtue of having in common a special technical feature, namely, a therapeutic composition as prescribed in claim 27.

Applicants therefore request (a) the lifting of the previous restriction as to method claims 1-12 and (b) their consideration with the elected composition claims.

IV. Traversal of rejections under 35 U.S.C. § 102

Claims 27-29, 31, 35-38 and 40 stand rejected for being allegedly anticipated by (i) Bhardwaj et al. (1996) as evidenced by Hackstein *et al*. (2002) or (ii) Kelleher *et al.* (1998). Applicants respectfully traverse these rejections, collectively, for the reasons that follow.

There is no dispute that the cited art neither teaches nor suggests a therapeutic (pharmaceutical) indication for the *in vitro* cultures they disclose. Rather, the examiner opines that the compositions of Bhardwaj and Kelleher could be interpreted as "therapeutic compositions" under the assumption that the referenced compositions "are not incompatible with biological activity." Although applicants disagree, they are mindful of the decision of Board of Patent Appeals and Interferences affirming the examiner's position.

The present claims have been amended, therefore, to prescribe that the recited composition "complies with standards of purity and quality control required for administration to humans." The cited prior art discloses compositions that cannot reasonably satisfy this proviso, because they comprise the following components, the presence of which contravenes "standards of purity and quality control required for administration to humans":

β-mercaptoethanol, which is toxic and is investigated as a mutagen. The Material Safety Data Sheet for β-mercaptoethanol recommends inducing vomiting to those who may ingest the chemical. [MSDS attached]

Fetal calf or human serum, which contains factors that may cause potentially serious reactions in patients [Lotze Declaration, para. 10] and, hence, would be deemed by regulatory authorities as an adulteration of anything "required for administration to humans."

In addition, dependent claims 41-53 recite pharmaceutical "structural" elements that are not found in or implicated for the prior-art compositions.

It is apparent, therefore, that the claimed compositions are not anticipated or presaged by the cited art. Reconsideration and withdrawal of the subject rejections are requested, therefore.

CONCLUSION

Applicants submit that this application is in condition for allowance, and they request an early indication to this effect. Examiner Juedes is invited to contact the undersigned directly, should she feel that any issue warrants further consideration.

The Commissioner is hereby authorized to charge any additional fee, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, then applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

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By /Stephen A. Bent/
Stephen A. Bent
Registration No. 29,768

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5404
Facsimile: (202) 672-5399